REMARKS/ARGUMENTS

The Official Action dated June 10, 2003 and referenced cited therein have been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested. This reply is being submitted with a Request for Continued Examination and a Supplemental Information Disclosure Statement.

Status of the prosecution:

The June 10, 2003 Official Action is a final rejection. Claims 16-26, 28 and 29 are pending. The requirement for a substitute Declaration has been withdrawn. The rejection of claim 18 under 35 U.S.C. §112, second paragraph, has been withdrawn. Claims 16-26, 28 and 29 remain rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. This is the sole ground of rejection remaining.

Current amendments to the specification and claims:

Claims 25, 26, 28 and 29 are canceled herein. Applicants note a previously undiscovered error in claim numbering, namely, claim numbers 21 and 22 were repeated. To address this error, the two latter claims numbered 21 and 22 have been re-numbered as claims 30 and 31. Each of claims 16-24, 30 and 31 are amended herein. Support for the amendments can be found in the specification. No new matter has been added. Applicants assert that the claims as amended are in condition for allowance, for the reasons set forth below.

The claims as amended are fully enabled by the specification:

Claims 16-26, 28 and 29 remain rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement on the ground that the claims recite an intended use of the compositions (claims 16-24) or method of use (claims 25, 26, 28, 29) for treatment of IDDM in humans, which is not enabled by the specification. Applicants traverse this rejection as applied to the currently amended claims.

Claims 25, 26, 28 and 29 have been canceled. The remaining claims have been amended such that they no longer recite an intended use for the claimed viral vectors. The specification is fully enabling for claims 1-24, 30 and 31 as amended. The currently amended claims are directed to a viral vector comprising a coxsackievirus genome modified to encode an attenuated coxsackievirus, the genome further comprising at least one cloning site for insertion of at least one expressible heterologous nucleic acid, wherein the heterologous nucleic acid encodes a biologically active immunomodulatory protein that induces a shift from a Th1 to a Th2 immune response. Examples 1 and 4 of the specification, along with the figures, disclose how to make and use a viral vector as recited in the claims. Examples 2, 3 and 7 of the specification sets forth an example of the claimed viral vector, comprising a heterologous nucleic acid that produces an immunolomodulatory protein known to induce a shift from a Th1 to a Th2 immune response. Example 7 further teaches the successful use of such a vector to induce a Th2 immune response in an animal model system of diabetes, thereby suppressing diabetes in the animals. Applicants assert that the specification provides ample enablement for one of skill in the art to make a use a viral vector as presently claimed. Accordingly, withdrawal of the rejection is respectfully requested.

Conclusion:

In view of the amendments submitted herewith and the foregoing remarks, the presently-pending claims are believed to be in condition for allowance. Applicants respectfully request early and favorable reconsideration and withdrawal of the objections and rejections set forth in the June 10, 2003 Action, and allowance of this application.

Respectfully submitted,

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This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1 – 15. Canceled.

16. (Currently amended) A ~~composition for treating an individual for insulin-dependent diabetes mellitus, which comprises:~~

[[a]] viral vector comprising a coxsackievirus genome modified to encode an attenuated coxsackievirus, the genome further comprising at least one cloning site for insertion of at least one expressible heterologous nucleic acid, wherein the heterologous nucleic acid encodes a biologically active immunomodulatory protein that induces a shift from a Th1 to a Th2 immune response ~~in the individual~~.

17. (Currently amended) The viral vector ~~composition~~ of claim 16, wherein the heterologous nucleic acid encodes IL-4.

18. (Currently amended) The viral vector ~~composition~~ of claim 16, comprising ~~wherein the viral vector comprises~~ a coxsackievirus B genome.

19. (Currently amended) The viral vector ~~composition~~ of claim 18, wherein the coxsackievirus genome is a coxsackievirus B3 genome.

20. (Currently amended) The viral vector ~~composition~~ of claim 19, wherein the coxsackievirus genome is modified by altering a transcription regulatory region of the genome.

21. (Currently amended) The viral vector ~~composition~~ of claim 19, wherein the transcription regulatory region comprises a 5' untranslated region of the genome.

22. (Currently amended) The viral vector ~~composition~~ of claim 21, wherein the 5' untranslated region is replaced with a 5' untranslated region of another enterovirus genome selected from the group consisting of poliovirus and echovirus.

23. (Currently amended) The viral vector ~~composition~~ of claim 16, wherein the cloning site is positioned between a coding sequence for a capsid protein and a coding sequence for viral protease.

24. (Currently amended) The viral vector ~~composition~~ of claim 16, wherein the cloning site is positioned at the start of the genome's open reading frame, and is constructed such that the inserted expressible heterologous DNA comprises a translation start codon and a 3' sequence recognized by a viral protease.

25 - 29. Canceled.

30 ~~21~~. (Currently amended) The viral vector ~~composition~~ of claim 19, wherein a uracil nucleotide at position 234 of the genome is replaced by a cytosine nucleotide or a guanine nucleotide.

31 ~~22~~. (Currently amended) The viral vector ~~composition~~ of claim 19, wherein a guanine nucleotide at position 233 of the genome is replaced by a cytosine nucleotide and an adenine nucleotide at position 236 of the genome is replaced by a uracil nucleotide.